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FAX



GlaxoSmithKline

To DO/EO/US

Company USPTO

Fax 571-273-3201

From Patricia Wilson

Tel 1-919-483-1007; Facsimile: 1-919-483-7988

E-mail patricia.t.wilson@gsk.com

Date Pages including cover 19

Subject Response to Notification of Missing Requirements

GlaxoSmithKline
PO Box 13398
Five Moore Drive
Research Triangle Park
North Carolina 27709

Tel: 919 483 2100
www.gsk.com

Re: Application of Konieczna et al.
Serial No.: 10/564,148; Int'l. Appl. No.: PCT/EP04/07667
Title: *Pharmaceutical Formulations Comprising Levothyroxine Sodium*
Attorney Docket No. PB60333USW

Attached is:

1. Transmittal Letter (2nd and 3rd pages in duplicate);
2. Declaration;
3. Copy of Notification of Missing Requirements under 35 USC 371, date mailed 4/20/2006;
4. Power of Attorney and Change of Correspondence Address Form;
5. Statement under 3.73(b); and
6. Corporate Resolution (POA).

Certificate of Transmission by Facsimile (37 CFR 1.8)

I hereby certify that this Response to Notification of Missing Requirements is being facsimile transmitted to the United States Patent and Trademark Office (Fax. No. 571-273-3201) on May 9, 2006.

Patty Wilson

The information contained in these documents is confidential and may also be privileged and is intended for the exclusive use of the addressee designated above. If you are not the intended recipient or the employee or agent responsible to deliver it to the intended recipient, any disclosure, reproduction, distribution, or any other dissemination or use of this communication is strictly prohibited. If you have received this transmission in error please contact us immediately by telephone so that we can arrange for its return.

| | | |
|--|---|---|
| FORM PTO-1390 (Modified) U.S. PATENT AND TRADEMARK OFFICE, U.S. DEPARTMENT OF COMMERCE (REV. 7-2005) | | ATTORNEY'S DOCKET NUMBER PB60333USw |
| TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371 | | U.S. APPLICATION NO. (If known, see 37 CFR 1.5) 10/564,148 |
| INTERNATIONAL APPLICATION NO. PCT/EP04/07667 | INTERNATIONAL FILING DATE July 8, 2004 | PRIORITY DATE CLAIMED July 10, 2003 |
| TITLE OF INVENTION Pharmaceutical Formulation Comprising Levothyroxine Sodium | | |
| APPLICANT(S) FOR DO/EO/US Malgorzata KONIECZNA, Heiner KROHN, Wanda TOMAN, Hendrik SCHLEHAHN and Malgorzata Anna STROZYK | | |
| Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: | | |
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. 2. <input checked="" type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. 3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (24) indicated below. 4. <input type="checkbox"/> The US has been elected (Article 31). 5. <input type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371 (c)(2)) <ol style="list-style-type: none"> a. <input type="checkbox"/> Is attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> has been communicated by the International Bureau. c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US). 6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). <ol style="list-style-type: none"> a. <input type="checkbox"/> is attached hereto. b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4). 7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3)) <ol style="list-style-type: none"> a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> have been communicated by the International Bureau. c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. d. <input type="checkbox"/> have not been made and will not be made. 8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). 9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)). 10. <input type="checkbox"/> An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 35 (35 U.S.C. 371 (c)(5)). 11. <input type="checkbox"/> A copy of the International Preliminary Examination Report (PCT/IPEA/409). 12. <input type="checkbox"/> A copy of the International Search Report (PCT/ISA/210). | | |
| Items 13 to 23 below concern document(s) or information included: | | |
| <ol style="list-style-type: none"> 13. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 14. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 15. <input type="checkbox"/> A FIRST preliminary amendment. 16. <input type="checkbox"/> A SECOND or SUBSEQUENT preliminary amendment. 17. <input type="checkbox"/> A substitute specification. 18. <input checked="" type="checkbox"/> A power of attorney and/or change of address letter. 19. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825. 20. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4). 21. <input type="checkbox"/> A second copy of the English language translation of the International Application under 35 U.S.C. 154(d)(4). 22. <input type="checkbox"/> Express Mail Label No. | | |

PTO-1390 (Rev. 07-2005)
Approved for use through 3/31/2007. OMB 0651-0021
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

| | | |
|---|--|--|
| U.S. APPLICATION NO (if known, see 37 CFR 1.5) 10/564,148 | INTERNATIONAL APPLICATION NO. PCT/EP04/07667 | ATTORNEY'S DOCKET NUMBER PB60333USw |
| 23. Other items or information: Statement under 3.73(b) Corporate Resolution (LOA) | | |
| The following fees have been submitted: 24. <input type="checkbox"/> Basic national fee \$300 | | CALCULATIONS PTO USE \$ \$0.00 |
| 25. <input type="checkbox"/> Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article \$0 All other situations \$200 | | \$ \$0.00 |
| 26. <input type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the international preliminary examination report by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4), ... \$0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the as an International Searching Authority \$100 International Search Report prepared by an ISA other than the US and provided to the previously communicated to the US by the IB \$400 All other situations \$500 | | \$ \$0.00 |
| TOTAL OF 24, 25 and 26 = | | \$ \$0.00 |
| <input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(i)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof. | | |
| Total Sheets | Extra Sheets | Number of each additional 50 or fraction thereof (round up to a whole) |
| - 100 = | () /50 = | () x \$250.00 |
| Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)). | | \$ \$0.00 |
| CLAIMS | NUMBER FILED | NUMBER EXTRA |
| Total claims | - 20 = | 0 x \$50.00 |
| Independent claims | - 3 = | 0 x \$200.00 |
| MULTIPLE DEPENDENT CLAIMS (if applicable) <input type="checkbox"/> + \$360.00 | | \$ \$0.00 |
| TOTAL OF ABOVE CALCULATIONS = | | \$ \$0.00 |
| <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2. | | \$ \$0.00 |
| SUBTOTAL = | | \$ \$0.00 |
| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)). | | \$ \$130.00 |
| TOTAL NATIONAL FEE = | | \$ 130 |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40 per property + | | \$ \$0.00 |
| TOTAL FEES ENCLOSED = | | \$ \$130.00 |
| Amount to be | | \$ |
| Amount to be | | \$ |

PTO-1390 (Rev. 07-2005)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

- a. ☐ A check in the amount of \$ _____ to cover the above fees is enclosed.
- b. ☒ Please charge my Deposit Account No. 07-1392 in the amount of \$ \$130.00 to cover the above fees.
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 07-1392. A duplicate copy of this sheet is enclosed.
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

CUSTOMER NO. 23347

Bonnie L. Deppenbrock
SIGNATURE
Bonnie L. Deppenbrock
NAME
28,209
REGISTRATION NUMBER
5/9/2006
DATE

PTO-1390 (Rev. 07-2005)

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| | | | | | |
|---|--------------|--|------------|--------------------------|-----------|
| U.S. APPLICATION NO (if known, see 37 CFR 1.5) | | INTERNATIONAL APPLICATION NO. | | ATTORNEY'S DOCKET NUMBER | |
| 10/564,148 | | PCT/EP04/07667 | | PB60333USw | |
| 23. Other items or information: Statement under 3.73(b) Corporate Resolution (POA) | | | | | |
| The following fees have been submitted: | | | | CALCULATIONS PTO USE | |
| 24. <input type="checkbox"/> Basic national fee | | | | \$300 | \$ \$0.00 |
| 25. <input type="checkbox"/> Examination fee (37 CFR 1.492(c)) | | | | | |
| If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) | | | | \$0 | \$ \$0.00 |
| All other situations. | | | | \$200 | |
| 26. <input type="checkbox"/> Search fee (37 CFR 1.492(b)) | | | | | |
| If the written opinion of the ISA/US or the International preliminary examination report by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) | | | | \$0 | \$ \$0.00 |
| Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the as an International Searching Authority. | | | | \$100 | |
| International Search Report prepared by an ISA other than the US and provided to the previously communicated to the US by the IB. | | | | \$400 | |
| All other situations. | | | | \$500 | |
| TOTAL OF 24, 25 and 26 = | | | | | \$ \$0.00 |
| <input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof. | | | | | |
| Total Sheets | Extra Sheets | Number of each additional 50 or fraction thereof (round up to a whole) | RATE | | |
| - 100 = | 0 /50 = | 0 | x \$250.00 | \$ | \$0.00 |
| Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)). | | | | \$ | |
| CLAIMS | NUMBER FILED | NUMBER EXTRA | RATE | | |
| Total claims | - 20 = | 0 | x \$50.00 | \$ | \$0.00 |
| Independent claims | - 3 = | 0 | x \$200.00 | \$ | \$0.00 |
| MULTIPLE DEPENDENT CLAIMS (if applicable) <input type="checkbox"/> + \$360.00 | | | | \$ | \$0.00 |
| TOTAL OF ABOVE CALCULATIONS = | | | | \$ | \$0.00 |
| <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2. | | | | \$ | \$0.00 |
| SUBTOTAL = | | | | \$ | \$0.00 |
| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)). | | | | \$ | \$130.00 |
| TOTAL NATIONAL FEE = | | | | \$ | 130 |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40 per property + | | | | \$ | \$0.00 |
| TOTAL FEES ENCLOSED = | | | | \$ | \$130.00 |
| | | | | Amount to be | \$ |
| | | | | Amount to be | \$ |

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- b. ☒ Please charge my Deposit Account No. 07-1392 in the amount of \$ \$130.00 to cover the above fees.
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 07-1392. A duplicate copy of this sheet is enclosed.
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

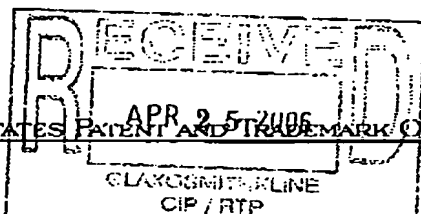
SEND ALL CORRESPONDENCE TO:

CUSTOMER NO. 23347

Ronnie L. Deppenbrock
SIGNATURE
Ronnie L. Deppenbrock
NAME
28,209
REGISTRATION NUMBER
5/9/2006
DATE



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| | | |
|-----------------------------|-----------------------|------------------|
| U.S. APPLICATION NUMBER NO. | FIRST NAMED APPLICANT | ATTY. DOCKET NO. |
| 10/564,148 | Malgorzata Konieczna | PB60333USw |

INTERNATIONAL APPLICATION NO.

PCT/EP04/07667

LA. FILING DATE

PRIORITY DATE

07/08/2004

07/10/2003

23347

GLAXOSMITHKLINE

CORPORATE INTELLECTUAL PROPERTY, MAI B475

FIVE MOORE DR., PO BOX 13398

RESEARCH TRIANGLE PARK, NC 27709-3398

CONFIRMATION NO. 6122

371 FORMALITIES LETTER

 OC000000018582853

Date Mailed: 04/20/2006

NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 01/10/2006
- Copy of the International Search Report filed on 01/10/2006
- Copy of IPE Report filed on 01/10/2006
- Preliminary Amendments filed on 01/10/2006
- Information Disclosure Statements filed on 01/10/2006
- Oath or Declaration filed on 01/10/2006
- Request for Immediate Examination filed on 01/10/2006
- U.S. Basic National Fees filed on 01/10/2006
- Priority Documents filed on 01/10/2006
- Specification filed on 01/10/2006
- Claims filed on 01/10/2006
- Abstracts filed on 01/10/2006

DOCKET-FEE

PB60333USW
 Docket No. BID/SJP
 Attorney: Declaration w/ Fee
 Paper: Declaration w/ Fee
 Due Date: 20 June 2006
 Deadline: 20 NOV 2006
 Recorded: 97

The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date. The current oath or declaration does not comply with 37 CFR 1.497(a) and (b) in that it:
 - is not executed in accordance with either 37 CFR 1.66 or 37 CFR 1.68.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.492(h) of \$130 for a non-small entity, must be submitted with the

missing items identified in this letter.

SUMMARY OF FEES DUE:

Total additional fees required for this application is \$130 for a Large Entity:

- \$130 Surcharge.

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

BARBARA A CAMPBELL

Telephone: (703) 308-9140 EXT 217

PART 1 - ATTORNEY/APPLICANT COPY

| U.S. APPLICATION NUMBER NO. | INTERNATIONAL APPLICATION NO | ATTY. DOCKET NO. |
|-----------------------------|------------------------------|------------------|
| 10/564,148 | PCT/EP04/07667 | PB60333USw |

FORM PCT/DO/EO/905 (371 Formalities Notice)

Docket No.: PB60333

DECLARATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

"PHARMACEUTICAL FORMULATION COMPRISING LEVOTHYROXINE SODIUM"

the specification of which (check one)

[...] is attached hereto.

[X] was filed on **08-Jul-2004** as Serial No. **PCT/EP2004/007667**
and was amended on (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the patentability as defined in Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) or Section 365(b) of any foreign application(s) for patent or inventor's certificate, or Section 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below any foreign application for patent or inventor's certificate, or PCT International application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)

| Number | Country | Filing Date | Priority Claimed |
|-----------|---------|-------------|------------------|
| 0316206.2 | GB | 10-Jul-2003 | YES |

I hereby claim the benefit under Title 35, United States Code, Section 119(e) of any United States provisional application(s) listed below.

| Application Number | Filing Date |
|--------------------|-------------|
|--------------------|-------------|

I hereby claim the benefit under Title 35, United States Code, Section 120 of any United States application(s) or Section 365(c) of any PCT International application designating

the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of Title 35, United States Code, Section 112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

| <u>Serial No.</u> | <u>Filing Date</u> | <u>Status</u> |
|-------------------|--------------------|---------------|
|-------------------|--------------------|---------------|

Direct all correspondence to the address associated with Customer Number 23347.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full Name of Inventor: Malgorzata KONIECZNA

Inventor's Signature: Malgorzata Konieczna

Date: 15 December 2005

Residence: Poznan, Poland

Citizenship: Polish

Post Office Address: GlaxoSmithKline
Corporate Intellectual Property
Five Moore Drive, P O Box 13398
Research Triangle Park
North Carolina 27709

Full Name of Inventor: Heiner KROHN

Inventor's Signature:  _____

Date: 06.01.2006

Residence: Bad Oldesole, Germany

Citizenship: German

Post Office Address: GlaxoSmithKline
Corporate Intellectual Property
Five Moore Drive, P O Box 13398
Research Triangle Park
North Carolina 27709

Full Name of Inventor: Wanda ROMAN

Inventor's Signature: _____

Date: _____

Residence: Poznan, Poland

Citizenship: Polish

Post Office Address: GlaxoSmithKline
Corporate Intellectual Property
Five Moore Drive, P O Box 13398
Research Triangle Park
North Carolina 27709

Full Name of Inventor: Heiner KROJIN

Inventor's Signature: _____

Date: _____

Residence: Bad Oldesole, Germany

Citizenship: German

Post Office Address: GlaxoSmithKline
Corporate Intellectual Property
Five Moore Drive, P O Box 13398
Research Triangle Park
North Carolina 27709

Full Name of Inventor: Wanda ROMAN

Inventor's Signature: Wanda Roman

Date: 15 FEBRUARY 2006

Residence: Poznan, Poland

Citizenship: Polish

Post Office Address: GlaxoSmithKline
Corporate Intellectual Property
Five Moore Drive, P O Box 13398
Research Triangle Park
North Carolina 27709

Full Name of Inventor: Hendrik SCHLEHAHN

Inventor's Signature: _____

Inventor's Signature: Shi Li

Date: 06.01.2006

Residence: Bad Oldesloe, Germany

Citizenship: German

Post Office Address: GlaxoSmithKline
Corporate Intellectual Property
Five Moore Drive, P O Box 13398
Research Triangle Park
North Carolina 27709

Full Name of Inventor: Malgorzata Anna STROZYK

Inventor's Signature: _____

Date: _____

Residence: Poznan, Poland

Citizenship: Polish

Post Office Address: GlaxoSmithKline
Corporate Intellectual Property
Five Moore Drive, P O Box 13398
Research Triangle Park
North Carolina 27709

Full Name of Inventor: Hendrik SCHUEHAHN

Inventor's Signature: _____

Date: _____

Residence: Bad Oldesloe, Germany

Citizenship: German

Post Office Address: GlaxoSmithKline
Corporate Intellectual Property
Five Moore Drive, P O Box 13398
Research Triangle Park
North Carolina 27709

Full Name of Inventor: Malgorzata Anna STROZYK

Inventor's Signature: Malgorzata Anna Strozyk

Date: 15 DECEMBER 2005

Residence: Poznan, Poland

Citizenship: Polish

Post Office Address: GlaxoSmithKline
Corporate Intellectual Property
Five Moore Drive, P O Box 13398
Research Triangle Park
North Carolina 27709

PTO/SB/81 (06-04)

Approved for use through 11/30/2005. OMB 0651-0035

U.S. Patent and Trademark Office: US DEPARTMENT OF COMMERCE

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| | | |
|---|-------------------------------|--|
| POWER OF ATTORNEY and CORRESPONDENCE ADDRESS INDICATION FORM | Application Number | PC/T/EP2004/007667 |
| | Filing Date | 08-Jul-2004 |
| | First Named Inventor | Malgorzata KONIECZNA |
| | Title | PHARMACEUTICAL FORMULATION COMPRISING LEVOTHYROXINE SODIUM |
| | Art Unit | |
| | Examiner Name | |
| | Attorney Docket Number | PB60333 |

I hereby appoint:

☒ Practitioners associated with the Customer Numbers. 23347

Or

☐ Practitioner(s) named below:

| Name | Registration Number |
|---|---------------------|
| As my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith. | |

Please recognize or change the correspondence address for the above-identified application to:

☐ The address associated with the above-mentioned Customer Number:

Or

☒ The address associated with Customer Number 23347

Or

☐ Firm or Individual Name:

| | |
|------------|-------------|
| Address: | |
| Address: | |
| City: | State: Zip: |
| Country: | |
| Telephone: | Fax: |

I am the:

☐ Applicant/Inventor:

☒ Assignee or record owner of the entire interest. See 37 CFR 3.71.

Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)

SIGNATURE of Applicant or Assignee of Record

| | |
|--|-----------------------------|
| Signature: | Date: 12 DEC 2005 |
| Name: Peter John GIDDINGS | Telephone: +44 20 8047 4414 |
| Title and Company: Attorney and Authorised Official, Glaxo Group Limited | |

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of: forms are submitted.

This collection of information is required by 37 CFR 1.31 and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is essential to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commission for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PTO/SB/81 (06-04)

Approved for use through 11/30/2005. OMB 0651-0035

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STATEMENT UNDER 37 CFR 3.73(b)

Applicant/Patent Owner: Glaxo Group Limited

International Application No./Patent No PCT/EP2004/007667 Filed/Issue Date: 08-Jul-2004

Entitled: PHARMACEUTICAL FORMULATION COMPRISING LEVOTHYROXINE SODIUM

Glaxo Group Limited, a corporation, states that it is:

1. ☒ the assignee of the entire right, title, and interest; or2. ☐ an assignee of less than the entire right, title and interest.

The extent (by percentage) of its ownership interest is _____ % in the patent application/patent identified above by virtue of either;

A. ☒ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel 017196, Frame 361, or for which a copy thereof is attached.

OR

B. ☐ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as shown below:1. From: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.2. From: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.3. From: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.☐ Additional documents in the chain of title are listed on a supplemental sheet.☐ Copies of assignments or other documents in the chain of title are attached.

[NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, if the assignment is to be recorded in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

Signature

12 DEC 2005

Date

Peter John GIDDINGS

Printed or Typed Name

+44 20 8042 4414

Telephone Number

Attorney and Authorized Official

Title

This collection of information is required by 37 CFR 1.31 and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is essential to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commission for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

APR 19 '05 02:39PM GLAXO WELLCOME

John Venn & SonsScrivener Notaries
TranslatorsWilliam P Kennah LL.B. - Ingrid M Reeve M.A. - Jonathan P Collins M.A., M.S.
Associate: Agnes Corkess
Contributor: Bridget M Ellison B.A.95 Aldwych London WC2B 4JF
United KingdomTelephone: 020 7395 4300
Fax: 020 7395 4310
e-mail: notary@johnvenn.co.uk
http://www.johnvenn.co.uk

I, JESSICA MARGARET REEVE, a duly admitted Notary Public, having jurisdiction throughout England and Wales and practising in London, England, hereby certify:

1. THAT the annexed Power of Attorney was sealed with the Common Seal of GLAXO GROUP LIMITED;

2. THAT the affixing of the said Seal was witnessed by LORRAINE ANNE DAY, one of the Directors of EDINBURGH PHARMACEUTICAL INDUSTRIES LIMITED, Corporate Director of GLAXO GROUP LIMITED and RICHARD JAMES STEPHENS, Assistant Secretary of the said GLAXO GROUP LIMITED;

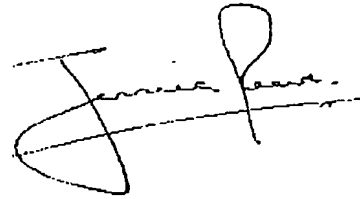
3. THAT the said GLAXO GROUP LIMITED is duly incorporated and existing under English Law, having its Registered Office at Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex, UB6 0NN, England;

4. THAT the said Seal was affixed in the manner prescribed by the current, duly adopted Articles of Association of the said Company;

5. THAT the said signatures were subscribed by authority of the Directors of the said Company;

6. AND THAT the said Power of Attorney, being so sealed and signed, is duly executed by and binding on the said Company.

IN WITNESS whereof I have issued this Certificate under my signature and Seal of Office at London, aforesaid, the fourth day of March Two thousand and five.




NPR 17 '05 02:39PM GLAXO WELLCOME

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Power of Attorney

BY THIS POWER OF ATTORNEY given this 20th day of ~~FEBRUARY~~ two thousand and five GLAXO GROUP LIMITED, a company incorporated in England and Wales (Registration No. 305979) and having its registered office at Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex, UB6 0NN, England (hereinafter called "the Company"), HEREBY appoints all and any of its Directors, Secretary and Assistant Secretary for the time being, and DAVID ROBERTS, PETER JOHN GIDDINGS, ARTHUR WILLIAM RUSSELL TYRRELL, MARCUS J. W. DALTON, PETER I. DOLTON, WENDY ANNE FILLER, MICHAEL JOHN STOTT, HUGH BAINFORDE DAWSON, HELEN QUILLIN, CHARLES KINZIG, STEPHEN VENETIANER, THEODORE R. FURMAN, MARY E. MCCARTHY, EDWARD R. GIMMI, CHARLES E. DADSWELL, ROBERT H. BRINK and FRANK P. GRASSLER jointly and severally to be its true and lawful agents and attorneys (hereinafter called "the Attorneys") on behalf and in the name of the Company or otherwise to do, perform, exercise or execute or concur with any other person or persons in doing, performing or exercising in or for any country or countries or jurisdiction in any part of the world all or any of the following powers, acts, deeds and things in connection with: letters patent, including extensions thereto, utility models; copyrights; trademark registrations; trademarks; trade names; trade dress; logos; design rights; designs and all rights analogous thereto and all applications therefor and any other forms whatsoever of Intellectual Property rights; including know-how, all of which are hereinafter called "Intellectual Property Rights", that is to say:

1. In any country or countries or jurisdiction in any part of the world to make application or cause application to be made for the grant or issue or transfer to the Company or registration in its name of Intellectual Property Rights and to take all steps necessary for the same to be prosecuted, maintained, withdrawn, renewed, enforced, defended or extended
2. As the act and deed of the Company to sign, seal, deliver and execute all or any assignments or assurances, licences to the Company of or under any Intellectual Property Rights or the right to and interest in any inventions to be the subject of Intellectual Property Rights for the purpose of fully and effectually vesting and transferring the same in and to the Company.
3. As the act and deed of the Company to sign and execute all or any assignments and acceptances of the transfer or assignment of such rights, and also any licences, sub-licences and consents from the Company of or under any Intellectual Property Rights or the right to and interest in any invention to be the subject of Intellectual Property Rights, for the purpose of fully and effectually vesting transferring or granting the same in and to any entity, whether in the United Kingdom or elsewhere, in so far as such documents can be executed without the Company's seal being affixed thereto. For purposes of this Power of Attorney, the terms "entity" means, and includes, any person, firm or company or group of persons or unincorporated body.
4. To give undertakings or assurances to third parties and to any Trademark Registry or official Intellectual property agency or governmental department or otherwise responsible for the registration or protection of trademarks, trade names, trade dress, logos, design rights or designs for the purpose of best protecting or ensuring the co-existence of the Company's rights to trademarks, trade names, trade dress, logos, design rights or designs.
5. To commence, prosecute and defend any proceedings or applications whether judicial or extra judicial relating to Intellectual Property Rights and to maintain, withdraw or settle the same.
6. For and in connection with any Intellectual Property Rights to sign, seal, deliver and execute any Power of Attorney or other deed or document authorising any agent,

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including trademark and patent agents and attorneys, to act on behalf of the Company.

7. To apply for the registration, amendment or cancellation of user rights in respect of any trademark or trade name.
8. To act in regard to all official communications which may now or hereafter be addressed to the Attorneys relating to Intellectual Property Rights or the renewal thereof in such manner that the Attorneys may be recognised as the authorised agent(s) of the Company in all proceedings in relation thereto.
9. For all or any of the purposes contained herein as the act and deed of the Company to sign, seal, deliver, execute and do all such documents, deeds, agreements, instruments and to do such acts as shall be requisite or may be deemed proper for or in relation to the said purposes.

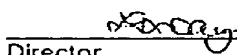
AND THE COMPANY HEREBY RATIFIES and confirms and agrees to ratify and confirm all and whatsoever the Attorneys or any person, persons, firm or company appointed by them shall lawfully do or have done by virtue of the authorities herein contained

AND THE COMPANY HEREBY DECLARES that all instruments executed under and by virtue of this Power shall be as valid and effectual as if sealed by the Common Seal of the Company.

IN WITNESS whereof **GLAXO GROUP LIMITED** has caused its Common Seal to be hereunto affixed the day and year first before written

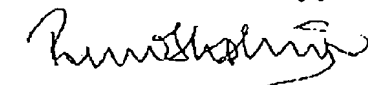
The **COMMON SEAL** of)
GLAXO GROUP LIMITED)
was hereto affixed in the presence of:)

Director



For and on Behalf of
Edinburgh
Pharmaceutical
Industries
Limited

DIRECTOR



Secretary / Assistant Secretary

